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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/831,846	08/21/2001	Shin-Ichi Funahashi	14875-081001/C2-010PCT-US	9799

7590 05/06/2004

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EXAMINER	
GUCKER, STEPHEN	
ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 05/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/831,846	FUNAHASHI ET AL.	
	Examiner	Art Unit	
	Stephen Gucker	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 February 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3 and 5-28* is/are pending in the application.

4a) Of the above claim(s) *1-3,5-9,15 and 20-28* is/are withdrawn from consideration.

5)☒ Claim(s) *10 and 16-18* is/are allowed.

6)☒ Claim(s) *11-14 and 19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Response to Amendment

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Any objections or rejections made in a previous Office Action that are not herein reinstated have been withdrawn.

3. Newly submitted claims 15 and 20-28 are directed to inventions that are independent or distinct from the invention originally claimed for the following reasons: new claims 15 and 20-22 are drawn to fusion proteins which are produced with an encoding DNA, so claims 15 and 20-22 belong to Group 1, the DNA group. New claims 23-26 are drawn to methods for screening for a compound which binds to a G protein-coupled receptor, so new claims 23-26 belong to Group 4, the screening method group. New claims 27-28 are drawn to methods of producing an antibody, so new claims 27-28 are drawn to new Group 6, methods of producing an antibody.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 15 and 20-28 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

4. Claims 11-14 and 19 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for SEQ ID NO:2 with or without its signal sequence, does not reasonably provide enablement for any additions to, deletions from, or substitutions to SEQ ID NO:2 (or functional equivalents that hybridize to the

complement of SEQ ID NO:2) for reasons of record and the following. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The specification does not adequately describe or provide guidance for variants or functional equivalents of SEQ ID NO:2 because no specific biological function is disclosed in the specification for SEQ ID NO:2, other than the instant protein might bind PDZ protein based on just 3 amino acid residues found in the carboxyl terminal of SEQ ID NO:2 and that the instant protein binds another protein of unknown function called "149Y2H#151". The unpredictability in the molecular biological protein art is high, and therefore the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved (*In re Fisher*, 166 USPQ 18). The disclosure only has a single example of a protein having the sequence of SEQ ID NO:2, and at this stage, the instant protein is only enabled as a marker for lung cancer as shown by its selective expression in A549 cells and not normal lung tissue (page 31 and Figure 1). All other uses for the protein are not enabled because the disclosure does not teach what ligands bind to the protein extracellularly in order to demonstrate its biological significance or function. Likewise, no working example is provided for the speculative assertion that the protein binds to PDZ protein intracellularly, or indeed, given the fact that the instant protein is an "orphan receptor" lacking any known ligand binding partners, what ligand could be used to induce the binding of PDZ protein to the instant protein. Given the lack of biological function demonstrated for the instant protein, its only enabled use is that of a lung cancer marker. A cancer marker does not have an

enabled use beyond the protein itself because the marker's only use is to differentiate between normal lung tissue and oncologies of the A549 type. A marker exists as a particular species of protein. A genus of proteins expanded in scope around a particular marker is not enabled because the marker's only enabled use is to differentiate between normal lung and cancerous lung, absent evidence that variants of the instant protein also are present in lung cancer tissue.

The specification is not enabled for protein variants comprising additions, deletions, or substitutions of amino acids because the functional equivalents of which amino acids can be changed from SEQ ID NO:2 and still retain biological functioning are not taught in the instant specification, other than the 3 amino acid residues identified in SEQ ID NO:2 that may allow PDZ binding. However, the skilled artisan could still use the instant invention with or without its signal sequence (amino acids residues 1-20) as a lung cancer marker, so new claims 16-18 are considered enabled.

Applicant's arguments filed 2/6/04 are not persuasive because Applicant argues from the point of view that the instant invention has utility other than as a lung cancer marker, and Applicant has failed to successfully rebut this aspect of the previous rejection. Although the artisan would be able to make the variants that Applicant argues for, the question then arises as to what the enabled use is of a variant when its only established utility is that of a particular cancer marker for a particular type of cell. The uses set forth by Applicant are merely uses for performing further research on the invention itself and do not rise to the level of a "real-world" use or utility. As stated previously, variants of cancer markers do not have a utility beyond the marker itself

unless a showing is made that variants of the instant invention do, in fact, appear in cancer cells. Otherwise, the variants are not enabled because the artisan does not know how to use a variant of a protein that appears in cancer cells, but has not been demonstrated to have any known biological function other than its presence in cancer cells. While the instant invention itself appears in cancer cells, no showing has been made that any variant of the instant invention appears in cancer cells, so the artisan would not know what to do with a variant of the instant invention.

5. Claims 10 and 16-18 are in condition for allowance.

6. As allowable subject matter has been indicated, applicant's reply must either comply with all formal requirements or specifically traverse each requirement not complied with. See 37 CFR 1.111(b) and MPEP § 707.07(a).

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technical Center 1600 general number which is (571) 272-1600.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen Gucker whose telephone number is (571) 272-0883. The examiner can normally be reached on Monday to Friday from 0930 to 1800. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached at (571) 272-0887. The fax phone number for this Group is currently (703) 872-9306.

SG

Stephen Gucker

May 3, 2004

Gary L. Kunz

GARY KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600